

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**APPLICATION FOR LETTERS PATENT**

\* \* \* \* \*

**COVERING FOR AN ASEPTIC TREATMENT SITE**

\* \* \* \* \*

INVENTORS

Joseph Hare  
Judson E. Threlkeld

ATTORNEY'S DOCKET NO. HA68-002

**EV318282985**

# **COVERING FOR AN ASEPTIC TREATMENT SITE**

## **TECHNICAL FIELD**

**[0001]** The present invention relates to a covering for an aseptic treatment site, and more specifically to a fenestrated surgical drape which has a portion that may remain in place after a surgical intervention and which will permit a clinician to continually observe and access, if necessary, the aseptic treatment site.

## **BACKGROUND OF THE INVENTION**

**[0002]** The prior art is replete with numerous examples of surgical drapes which have been designed and utilized, through the years, to aid clinicians in the treatment of patients having various maladies. Typically, such surgical drapes have been adapted for use with a wide variety of electronic and mechanical devices which are used for treating the patient's medical conditions. Depending on the nature of the condition, such medical devices, can for example, be surgically implanted, connected externally to the patient receiving treatment, or even used during a surgical technique.

**[0003]** Fenestrated surgical drapes have been used, heretofore, to maintain sterile conditions, maintain patient privacy, absorb bodily fluids, and further provide a clear and clean work area for the clinician. The prior art surgical drapes, such as the one shown in Fig. 1 employ a fenestration or opening in the surgical drape which provides the clinician with access to the desired site on the patient's body while preserving the function of the surgical drape which is utilized to cover other areas of the patient's body.

**[0004]** In a typical utilization of such fenestrated surgical drapes, a medical treatment site, such as a surgical site is located, and thereafter the site is prepared for surgery by making it substantially aseptic. Thereafter, the surgical drape having the fenestration is placed over the surgical site and the medical procedure or surgery is initiated. Following completion of the surgery, the typical practice is to remove the entire surgical drape because portions of the drape may have absorbed body fluid during the surgery. The patient is then moved from the surgical theater to a recovery room. Some surgical procedures require that the surgical site be monitored for a period of time in order to detect any abnormalities in the recovery of the patient. On some occasions, irregularities may occur either at the surgical site, or elsewhere in the patients' body which indicate that the previous surgical procedure has been unsuccessful or another situation has arisen in the patient's body which indicates that further surgical intervention is required by the clinician. In these circumstances, immediate surgical intervention is not possible inasmuch as the original surgical site is no longer in an aseptic condition. Consequently under these conditions, the surgical site must be again rendered aseptic before a clinician can gain access to same. This time delay to render a surgical site aseptic can be significant, and may under some circumstances be life threatening.

**[0005]** Therefore, a covering for an aseptic treatment site which addresses the perceived shortcomings of the prior art practices and devices utilized heretofore is the subject matter of the present application.

## SUMMARY OF THE INVENTION

**[0006]** A first aspect of the present invention relates to a covering for an aseptic treatment site which includes, a substrate defining an aperture which permits selective access to an aseptic treatment site on a patient; and a transparent cover borne by the substrate and which is removably affixed in substantially aseptic covering relation relative to the aperture.

**[0007]** Another aspect of the present invention relates to a covering for an aseptic treatment site which includes, a flexible substrate having opposite first and second surfaces, and which defines an aperture which permits access to an aseptic treatment site on a patient; a first adhesive region borne on the second surface of the flexible substrate, and which substantially surrounds the aperture; a flexible transparent cover moveably affixed on the first surface of the flexible substrate, and which is moveable along a course of travel between a first, covering position relative to the aperture, and which permits observation of the aseptic treatment site, to a second, uncovered position relative to the aperture, and which permits access to the aseptic treatment site; and a second adhesive region borne by the flexible, transparent cover, and which releasably adhesively affixes the flexible transparent cover to the first surface of the flexible substrate.

**[0008]** Yet another aspect of the present invention relates to a covering for an aseptic treatment site which includes, a flexible substrate having a first region, and a releasably detachable second region, and wherein the first region defines an aperture which permits access to an aseptic treatment site on a patient; a first adhesive region substantially surrounding the aperture, and which is borne by the first region, and wherein the first adhesive region releasably adhesively affixes the first region on the

body of the patient in an orientation such that the first region surrounds the aseptic treatment site; a flexible transparent cover hingedly affixed on the first surface of the flexible substrate, and wherein the transparent cover has a peripheral edge, opposite first and second surfaces, and opposite first and second ends, and wherein the second end of the flexible transparent cover is hingedly affixed on the first surface, and wherein the first end is moveable along a substantially arcuately shaped path of travel between a first position, wherein the transparent cover is disposed in a covering relation relative to the aperture and substantially out of direct contact with the aseptic treatment site, to a second position, wherein the transparent cover is disposed in an orientation which allows access to the aseptic treatment site by way of the aperture; and a second adhesive region disposed on either one of the transparent cover or the substrate and which releaseably adhesively affixes the peripheral edge of the transparent cover on the substrate and in the first covering position relative to the aperture, and wherein the second adhesive region releases the transparent cover from the first position when force is applied to the first end of the transparent cover, and wherein the second adhesive region permits the transparent cover to be repeatedly moved between the first and second positions without substantially adhesively detaching the first adhesive region from the patient.

**[0009]** These and other aspects of the present invention will be discussed in greater detail hereinafter.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0010]** The accompanying drawings serve to explain the principles of the present invention.

**[0011]** Fig. 1 is a bottom plan view of a prior art surgical drape.

**[0012]** Fig. 2 is a top plan view of the covering for an aseptic treatment site of the present invention.

**[0013]** Fig. 3 is a partial, fragmentary top plan view of the covering for an aseptic treatment shown positioned on a patient's limb.

**[0014]** Fig. 4 is a fragmentary, somewhat enlarged, top plan view of the covering for an aseptic treatment site with a transparent cover shown in a covered position.

**[0015]** Fig. 5 is a fragmentary, top plan view of the covering for an aseptic treatment site with a transparent cover mounted on same shown in an uncovered position.

**[0016]** Fig. 6 is a fragmentary, perspective, view of the covering for an aseptic treatment site with one portion detached.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

**[0017]** This disclosure of the invention is submitted in furtherance of the constitutional purposes of the U.S. Patent Laws "to promote the progress of science and useful arts" (Article 1, Section 8).

**[0018]** The covering for an aseptic treatment site of the present invention is generally indicated by the numeral 10 in Fig. 2 and following. Referring as a first matter to Fig. 1, a prior art, commercially available angiography drape is shown therein and is designated by the numeral 11. This prior art drape 11 includes a main body 12 which is typically fabricated, at least in part, from a cellulosic substantially opaque material. The main body 12 has a first end 13 which is typically oriented towards the head of the patient, and an opposite second end 14, which is positioned near the feet of a patient.

The main body 12 is defined by a peripheral edge 15. A transparent pliable perimeter portion 20, is provided, and which is attached to the peripheral edge 15. This perimeter portion includes a plurality of deformable attachment members 21 which are adhesively affixed to the pliable perimeter and which can be deformed in order to secure the perimeter to an adjacent object such as an examination table. These deformable attachment members are bent or otherwise deformed in order to attach the perimeter to the object, thereby securing the drape in an orientation such that it is secured out of the way of the clinician and other healthcare workers working adjacent thereto. The main body 12 includes a pair of windows, apertures or fenestrations 22 which are formed in predetermined positions near the first end 31, and which provide a convenient location whereby a clinician may gain access to the patient's body positioned below the surgical drape in order to perform medical procedures. As should be understood, the windows or apertures formed in the main body 12 are occluded, in part, by a flexible transparent adhesive border 23 which is affixed to the main body 12 and which defines an aperture 24 through which the clinician will gain access to the patient's body. A release paper of conventional design 25 is releasably positioned in covering relation relative to the flexible transparent adhesive border 23. This release paper 25 is removed thereby exposing the adhesive border therebelow. Thereafter, the clinician positions the aperture 24 in an appropriate orientation and the flexible transparent adhesive border 23 secures the main body 12 in place such that it does not move during the medical procedure.

**[0019]** Referring now to Fig. 2, the covering for an aseptic treatment site of the present invention and which is designated by the numeral 10 is shown in a top plan view. As seen in Fig. 2 and following, the invention includes a main body 30 which is

fabricated, at least in part, from a cellulosic substrate which is substantially opaque. The main body 30 provides an aseptic barrier and is also capable of absorbing body or other fluids which might be generated during a surgical or other medical procedure. The main body 30 has a first end 31 which is typically oriented at the head of a patient, (not shown) and a second end 32 which is oriented typically at or toward the feet of a patient. The main body 30 is defined by a peripheral edge 33. Similar to the prior art device shown in Fig. 1, a transparent pliable perimeter portion 34 is provided. This perimeter portion also includes deformable attachment members 35 which operate in a fashion similar to that described with respect to the prior art device shown in Fig. 1.

**[0020]** Referring still to Figs. 2 and 6, the present invention 10 includes a pair of regions generally indicated by the numeral 40. The pair of regions includes a first region 41 and a selectively detachable second region 42 which is joined to the first region. As seen in Fig. 2 and following, the selectively detachable second region comprises a preponderance of the main body 30. A plurality of perforations or weakened areas 43 are formed in a pattern in the second region 42 and which surround, at least in part, the first region 41. As will be appreciated from the discussion which follows, this plurality of weakened areas or other perforations further facilitate the detachment of the second region 42 from the first region 41. As noted above, the main body 30 is typically fabricated, at least in part, from a cellulosic substrate, and the plurality of perforations or weakened areas which define a periphery of the first region, permits the second region to be removed from the first region by tearing the main body along the perforations. The first region 41 includes a first portion 44 which defines an aperture 45; and a second portion 46 which is made integral with the first portion. As seen in Fig. 2 and following, the second region 42 is selectively detachable relative to



the second portion 46. As should be understood, the second region 42 and the second portion 46 may be fabricated from the same material, or from different materials as the needs require. Yet further, the first and second portions 44 and 46 may be fabricated from the same materials or from different materials depending upon the construction and end use of same.

**[0021]** The first portion 44 which defines the aperture 45 has a first surface 50 and an opposite second surface 51 (Fig. 5). The second surface 51 has an adhesive coating 52 applied thereto. The adhesive coating 52 is operable to adhere the first portion 44 to a patient's body and in a given position such that it surrounds a surgical or medical intervention site 53 as seen in Fig. 3. The adhesive coating 52 has a predetermined adhesive strength. This surgical intervention site 53 may be on a limb 54 as shown in Fig. 3, or on the torso of a patient (not shown). As seen in Fig. 2 and following, the present invention 10 includes a transparent cover 60 which is moveably borne by the first portion 44, and which is removably affixed in a substantially aseptic covering relation relative to the aperture 45 (Fig. 3 and 4). In particular, it will be seen from a study of Figs. 4 and 5 that the transparent cover 60 is hingedly mounted on the first portion 44. The transparent cover 60 has a first end 61 which may be grasped by a clinician, and an opposite second end 62 which is hingedly mounted to the first portion 44. Still further, the transparent cover includes a first surface 63 and an opposite second surface 64. The transparent cover defines a cavity 65 which, when the cover is placed in an appropriate orientation in covering relation relative to the aperture 45, ensures that the cover does not directly contact the surgical intervention site 53. The transparent cover as seen in Fig. 3 permits the clinician to continuously view the surgical intervention site while maintaining the surgical intervention site 53 in an aseptic

condition. An adhesive layer 66 is provided, and which is applied in a given pattern on the second surface 64. This adhesive layer 66 is operable to adhesively attach the cover 60 in covering relation relative to the aperture 45 by adhering the cover to the area of the first portion 44 which is adjacent to the aperture 45. This adhesive layer 66 has adhesive strength which is less than the adhesive strength provided by the adhesive coating 52. This permits the cover 60 to be repeatedly moved between the first and second positions 71 and 72 without pulling the first portion 44 away from the aseptic treatment site 53. The transparent cover 60 is moveable along a substantially arcuately path of travel indicated by the numeral 70. The path of travel is defined between a first position 71 wherein the transparent cover is disposed in substantially covering relation relative to the aperture (Fig. 4), and a second position 72 wherein the transparent cover 60 allows access to the aseptic treatment site.

## OPERATION

**[0022]** The operation of the described embodiment of the present is believed to be readily apparent and is briefly summarized at this point.

**[0023]** The present invention relates to a covering for an aseptic treatment site 10 and is best understood by Fig. 2 and following. As shown therein, the invention includes a substrate defining a first portion 44 which permits selective access to an aseptic treatment site on a patient and which defines an aperture 45; and a transparent cover 60 is borne by the substrate and which is removably affixed in substantially aseptic covering relation relative to the aperture 45. More particularly, the present invention 10 relates to a covering for an aseptic treatment site 53 which includes a flexible substrate defining a first portion 44, having opposite first and second surfaces

50 and 51, and which defines an aperture 45 which permits access to an aseptic treatment site 53 on the patient. Still further, a first adhesive region 52 is borne on the second surface of the flexible substrate defining the first portion 44, and which substantially surrounds the aperture 45. A flexible transparent cover 60 is moveably affixed on the first surface 50 of the first portion 44, and which is moveable along a course of travel 70 between a first, covering position 71 relative to the aperture 45, and which permits observation of the aseptic treatment site 53, to a second, uncovered position relative to the aperture, and which permits access to the aseptic treatment site. Further, a second adhesive region 66 is borne by the flexible, transparent cover, and which releasably adhesively affixes the flexible transparent cover to the first surface 50 of the flexible substrate defining the first portion.

**[0024]** In the present invention, a covering for an aseptic treatment site 10 includes a flexible substrate defining a main body 30, having a first region 41, and a releasably detachable second region 42. The first region defines an aperture 45 which permits access to an aseptic treatment site on a patient 53. A first adhesive region 52 substantially surrounding the aperture 45, and is borne by the first region. The first adhesive region releasably adhesively affixes the first region 41 on the body of the patient in an orientation such that the first region surrounds the aseptic treatment site 53. A flexible transparent cover 60 is provided and hingedly affixed on the first surface 50 of the flexible substrate. The transparent cover has a peripheral edge, opposite first and second surfaces 63 and 64, and opposite first and second ends 61 and 62. As seen in the drawings, the second end 62 of the flexible transparent cover 60 is hingedly affixed on the first surface 50. The first end 61 is moveable along a substantially arcuately shaped path of travel 70 between a first position 71, wherein the transparent

cover 60 is disposed in covering relation relative to the aperture 45, and substantially out of direct contact with the aseptic treatment site 53, to a second position 72, wherein the transparent cover 60 is disposed in an orientation which allows access to the aseptic treatment site 53 by way of the aperture 45. A second adhesive region 66 is disposed on either one of the transparent cover 60 or the first region 41 and which releaseably adhesively affixes the transparent cover on the substrate and in the first covering position 71 relative to the aperture 45. The second adhesive region releases the transparent cover from the first position when force is applied to the first end 61 of the transparent cover. The second adhesive region permits the transparent cover to be repeatedly moved between the first and second positions 71 and 72 without substantially adhesively detaching the first adhesive region 52 from the patient.

**[0025]** Therefore it will be seen that the present invention provides many advantages over the prior art surgical drapes which have been utilized heretofore inasmuch as a clinician may maintain an aseptic treatment site long after a patient has been removed from a surgical theater by merely detaching the second region 42 from the first region 41, and thereafter observing the surgical intervention site through the transparent cover 60. In the event that further intervention is required by the clinician, the patient may be moved back into a surgical theater and intervention may commence by removing the transparent cover without need for further aseptic treatment of the site.

**[0026]** In compliance with the statute, the invention has been described in language more or less specific as to structural and methodical features. It is to be understood, however, that the invention is not limited to the specific features shown and described, since the means herein disclosed comprise preferred forms of putting the invention into effect. The invention is, therefore, claimed in any of its forms or

modifications within the proper scope of the appended claims appropriately interpreted in accordance with the doctrine of equivalents.